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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,215	02/19/2004	James A. McClain	030900	5338
41835	7590	06/13/2006	EXAMINER KRISHNAN, GANAPATHY	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP HENRY W. OLIVER BUILDING 535 SMITHFIELD STREET PITTSBURGH, PA 15222			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,215	MCCLAIN, JAMES A.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/04,07/04,10/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Request for Continued Examination filed 3/27/2006 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2, 5, 8, 11, 17 and 25 have been canceled.
2. Claims 1, 23-24 and 27 have been amended.
3. Remarks drawn to rejections under 103

Claims 1-27 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6-7, 9-10, 12-16 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1(d) recites, “until a maximum yield of resistant starch has been obtained”.

Maximum yield in any process is considered 100% yield of the desired product. It is not clear if applicant intends 100% yield of the said product or the maximum yield could be less than 100%. For the purpose of prosecution any yield upto 100% is interpreted as maximum.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-4, 6-7, 9, 12-16, 18, 20-24 and 26-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 12-15, 18-23, 26-31 and 33-34 of copending Application No. 10/959,792 ('792 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a method of producing resistant starch comprising acidifying unmodified starch to a pH of about 1 to about 4 with HCl, heating the acidified starch to the temperature range of about 140°C to about 180°C and maintaining the acidified unmodified starch at the said temperature till a maximum yield is obtained while maintaining a whiteness level between 60 and 100. Claim 1 of the copending '792 application is also drawn to a similar process, with claims 2-7 reciting limitations drawn to the temperature range and pH range that overlap with those recited in instant claim 1.

Instant claims 3-4 recite hydrochloric acid as the acidifying agent. Copending claim 12 also recites hydrochloric acid as the acidifying agent.

Instant claims 1 and 12 recite a range for the whiteness level , which overlaps with the whiteness levels recited in copending claims 12-15.

A similar overlap is seen between the process steps and limitations recited in instant claims 13-18, 20-24 and 26-27 and those of copending claims 18-23, 26-32 and 33-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that instant Claims 1, 3-4, 6-7, 9, 12-16, 18, 20-24 and 26-27 and copending claims 1-7, 12-15, 18-23, 26-31 and 33-34 are substantially overlapping. The product obtained and its utility is also similar. Instant Claims 1, 3-4, 6-7, 9, 12-16, 18, 20-24 and 26-27 should recite limitations that are patentably distinct from those of copending claims 18-23, 26-32 and 33-34.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohkuma et al (US 5,358,729) in combination with Wurzburg (Modified Starches: Properties and Uses, CRC Press Inc., 1986, 33-34) and Bulfer (US 2,287,599).

Ohkuma et al teach a process for producing a resistant starch by selecting a reaction temperature, acidifying the starch, heating acidified starch to the selected temperature and maintaining the temperature of acidified starch close to the reaction temperature to avoid coloring (abstract; col. 1, lines 6-10; col. 5, line 67 through col. 6, line 68). Ohkuma teaches the use of hydrochloric acid for the acidification of starch (col. 6, line 41). Ohkuma emphasizes that the whiteness decreased in inverse proportion to the heating temperature or heating time (co. 23, line 37). The reaction temperature is 120-200°C and more preferably 140-180°C (col. 6, line 66). Example 5 (col. 31) of Ohkuma use starch having a moisture content of 5% and the resistant starch recovered is over 60% (col. 5, lines 7-10). The degree of whiteness attained in Ohkuma's process ranges from 12.3 to 66 (Example 4). Even though Ohkuma et al do not teach a correlation between the pH and the whiteness, if one compares the figures 2 and 3 of Ohkuma, it can be seen that at a pH of 4.5 the degree of coloration at pH 4.5 is less compared to that at pH 6.5. This means that the whiteness level is more at pH 4.5 (less coloration) compared to that at pH 6.5. One of ordinary skill in the art would recognize from this disclosure of Ohkuma that lowering the pH decreases the coloration and thereby increases whiteness level. However, Ohkuma et al do not teach resistant starch with a whiteness level of over 66.

Wurzburg, drawn to modified starch and its properties, teaches that the color of dextrin ranges from near white to dark brown and is an indication of the temperature to which the starch is exposed during dextrinization and is also influenced by the acidity of the starch (page 34, #3, Color). This teaching of Wurzburg indicates that the whiteness is affected by acidity or in other words pH. However, Wurzburg does not teach process steps for producing the said starch.

Bulfer teaches a method for producing resistant white starch via an acidification process that is conducted at a temperature range of 94-177°C and a pH of 2.7. However, the acidification is performed using chlorine gas.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the prior art methods of Ohkuma and Bulfer to produce resistant starch including a means to generate the whiteness as suggested by Wurzburg and Ohkuma.

One of ordinary skill in the art would be motivated to do so because Ohkuma teaches the starch has beneficial effects if consumed but often has unpleasant odor due to coloration (col. 2, lines 35-39; col. 27-41; col. 5, lines 1-10). The method of prior art would produce a resistant starch that is superior and does not have an unpleasant odor and also does not involve extensive purification.

Response to Applicant's Remarks

Applicant has argued previous rejection that the instant invention is not obvious over Ohkuma and Bulfer because the prior art teaching does not render obvious the instant process produces a product that has a high whiteness, which is a commercially desirable property and

such a product is not obtained by the prior art process. The rejection using prior art as presented above renders the instant process obvious and also provides the motivation to do so.

Conclusion

Claims 1-27 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



6/7/06

Shaojia Jiang
Supervisory Patent Examiner
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